Rocketmedical

SERVICE MANUAL

Rocket Digital Oocyte Aspiration Pump

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2. GENERAL ASSEMBLY

2.1. Rocket Digital Oocyte Aspiration Pump

Rocket Digital Oocyte Aspiration Pump

1. Touch sensitive Suction Control Dial – clockwise to increase, anticlockwise to decrease the set value
2. Suction Display in $mmHg^{-1}$
3. Patient connection port – only for use with R57686 Rocket Oocyte Aspiration Pump Patient Connection Sets
4. Power On Indicator LED (Green, 12VDC)
5. Footswitch connection ports
6. User Set Suction Indicator LED (Blue,50-300$mmHg^{-1}$)
7. Pre-set (Max) Suction Indicator LED (Orange, 500$mmHg^{-1}$)
8. Service Indicator LED (Yellow)
9. O/I 12V Power On/Off switch
10. Dual footswitch – air controlled

Not shown:

11. Power Supply Unit (PSU) Model: MPU30B-3
12. Power cords, IEC UK & EC types.

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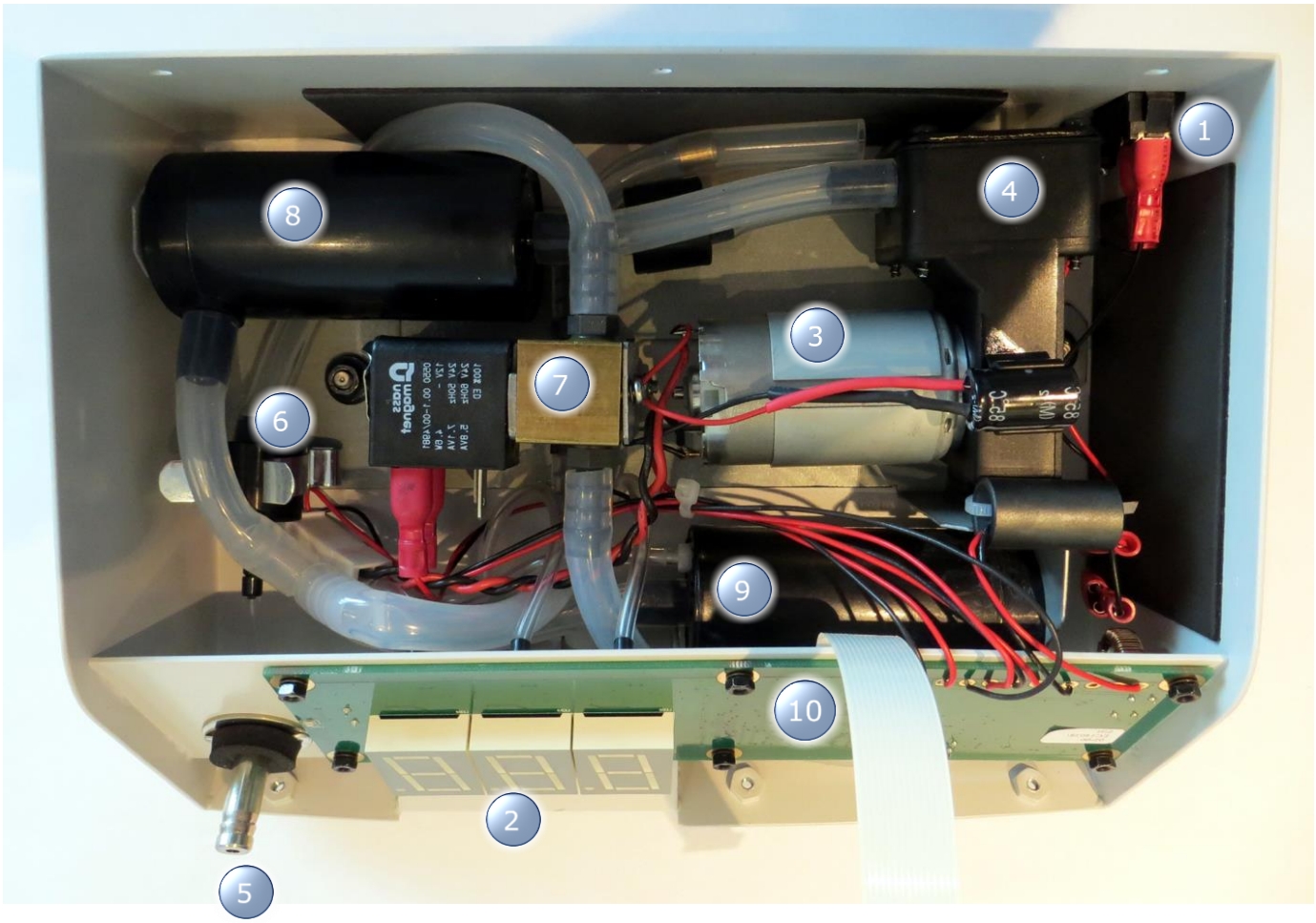
2.2. Rocket Digital Oocyte Aspiration Pump – Internal View



1. O/I Mains Power On/Off
2. Vacuum display 0-500mmHg^{-1} – normal range 50-300mmHg^{-1}
3. Motor 12V
4. Pump head including valve housing
5. Vacuum outlet port
6. Vacuum inlet filter
7. Vacuum control solenoid
8. Internal silencer with filter chamber (A)
9. Internal silencer with filter chamber (B)
10. Internal exhaust vent and filter
11. Control PCB with ribbon cable to vacuum control touch wheel

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3. GENERAL DESCRIPTION:

The Rocket Oocyte Aspiration Pump has been developed to provide smooth, low volume/high suction (vacuum) at a pre-determined negative pressure. Suction is activated by a foot operated toggle air switch controlled by the surgeon performing the oocyte collection.

The range of suction is variable from 50-300mmHg^{-1} and at a pre-set 500mmHg^{-1} in 'Max' suction mode.

The Rocket Oocyte Aspiration Pump requires a disposable filter set for attachment of the pump to the oocyte collection needle. The filter set is supplied separately, sterile and for single patient use.

You will also require:

- A suitable oocyte aspiration needle such as Rocket SX Single Lumen Oocyte Aspiration Set (R57602-00-90)
- Suitable collection tubes for use with oocyte needle sets such as B.D. Falcon test tube No. 2001F, 17 x 100mm.
- Flushing media

3.1. INDICATIONS:

For the generation of high vacuum/low volume suction between 50-500 mmHg^{-1} to permit the aspiration of follicular fluid, oocytes and ovarian fluid as part of the treatment of infertility relating to IVF and other gynaecological procedures.

3.2. CONTRAINDICATIONS:

Not intended for use where ovarian aspiration or the aspiration of ovarian fluid is contraindicated. For short term operation only. The device is NOT intended for continuous drainage.

3.3.CLASSIFICATION

- IEC 60601-1: 2005
- Type of protection against electric shock: Class II
- Degree of protection against electric shock: Type B
- Vacuum type: high vacuum/low volume
- Suitable for continuous operation.
- Not suitable for use in the presence of flammable gases.
- Not suitable for use in conditions which expose the device to the ingress of fluids.
- Not suitable for sterilisation

3.4. REFERENCES:

Craft I, McLeod F. Edmonds K, 'Human embryo transfer technique'. Lancet 1961 ii 1104-5

Craft I, Diahanbakch O. McLeod F et al 'Human pregnancy following oocyte and sperm transfer to the uterus.' Lancet 1992 i 1031-3

Craft I, (1984) 'Clinical Methodology' British Journal of Hospital Medicine 90-102

Reeves G, Scott R T, et al (1989) Journal of Assisted Reproduction and Genetics Volume 6, Number 6 / December, 1989

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WARNING: READ THIS MANUAL CAREFULLY: *Please familiarise yourself with the contents of this manual before attempting to use the device.*

Failure to observe these instructions may result in damage to the pump or cause injury to the patient or user.

This device should only be used by suitably qualified personnel.

4. GENERAL INFORMATION

4.1. COPYRIGHT

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This manual should not be photocopied, duplicated or distributed completely or in part without the written approval of Rocket Medical plc.

4.2.MODEL NUMBER:

Rocket Digital Suction Pump Complete (110v)	**R29700**
Power supply:	MPU30B-3

4.3. MANUAL REVISION:

Revision 1	First Publication	05/11/13
Revision 2	Update of LRQA CE mark	27/08/14
Revision 3	Pump timer zero procedure	15/07/15

WARNING: ELECTRIC SHOCK HAZARD.
The equipment is to be used only with electrical systems complying with all IEC, CEC and NEC requirements.

4.4. MANUFACTURER:

Rocket Medical plc Sedling Road WASHINGTON Tyne & Wear NE38 9BZ UK.	CE 0088

CAUTION: *Any adjustment, modification or repairs to the equipment should be carried out by authorised service agents.*

4.5. SERVICE AGENTS:

Rocket Digital Pumps typically require only annual maintenance; however it is recommended they are serviced and calibrated annually at a **Rocket Medical plc** approved service facility.

Failure to service the pump at the indicated intervals may invalidate the Warranty.

Customer Services:
Rocket Medical plc.
Sedling Road. WASHINGTON. NE38 9BZ. ENGLAND

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Email: homesales@rocketmedical.com

Disposal of this device must be undertaken with regard to the WEEE directive (2002/96/EC).

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WARNING: ELECTRIC SHOCK HAZARD.
The equipment is to be used only with electrical systems complying with all IEC, CEC and NEC requirements.

4.6. SUPPLY VOLTAGE SELECTION

The device is only for use with power supply Model Number: MPU30B-3. Attachment of any other power supply may severely damage the device.

CAUTION: Disconnection from the mains supply can only be achieved with the removal of the mains power lead from the wall socket.

The device operates at a voltage 110V 60Hz or 220-240 VAC @ 50Hz. 0.12A

4.7.ELECTROMAGNETIC COMPATIBILITY

Rocket Craft Suction Pumps comply with the electromagnetic compatibility (EMC) limits for medical devices as specified by IEC 60601-1-2:2001. These limits are designed to provide a reasonable degree of protection against harmful interference found in typical medical installations.

Medical electrical equipment requires special precautions regarding EMC and the device must be installed, positioned and operated according to the instructions contained in this manual to ensure continued electromagnetic compatibility.

The device must be operated according to the instructions contained in this manual to ensure continued electromagnetic compatibility.

WARNING: ELECTRIC SHOCK HAZARD.
Do not immerse the device.

4.8.PACKAGING

The packaging has been designed to allow secure transportation of the pump and its accessories.

After unpacking, re-assemble and retain the packaging for transport for servicing when required.

WARNING:
Device can cause explosion in the presence of flammable gases.

4.9. POSITIONING and PLACEMENT of the DEVICE

Rocket Digital Oocyte Aspiration Pumps must be placed on a secure, level surface, away from sources of heat, water splashes, mists or cooling vents.

Do not expose to direct sunlight.

Do not expose to flammable gases.

Operating temperature Range: +5°C and +35°C

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4.9. SYMBOLS USED ON OOCYTE ASPIRATION PUMP.

	12 V DC Power ON/OFF. **This device operates on 12V DC power provided by a separate power supply module supplied with the device.** Disconnection from the mains supply can only be achieved with the removal of the mains power lead from the wall socket.
	This device is Type B
	Connection point for filter set
	This device is powered by a Class II power supply unit.
	Indicates the Service Interval Indicator
	Suction Display Touch control symbol.
	Indicates activation of the pre-set (Max) 500mmHg^{-1} mode
	Indicates activation of the user set 50-300mmHg^{-1} mode
	Dispose of this device in accordance with WEEE directive (2002/96/EC)
	CE Mark

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4.10. SYMBOLS USED ON POWER SUPPLY UNIT.

	Read the manual before connection and use
	WARNING: Risk of electric shock. The PSU should not be opened
	Device is only for use indoors
	Class II Power Supply Unit
	12V DC connection polarity
	Dispose of this device in accordance with WEEE directive (2002/96/EC)
	PSU conforms to EN60601-1 & IEC60601-1
	CE Mark

4.11. SYMBOLS USED ON R57686 PATIENT CONNECTION SET.

	Read the Instruction for Use before connection and use
	Device is for Single Use Only
	Batch number for sterile device
	Device is sterilised by Ethylene Oxide
	The device is not manufactured with natural latex
	CE Mark

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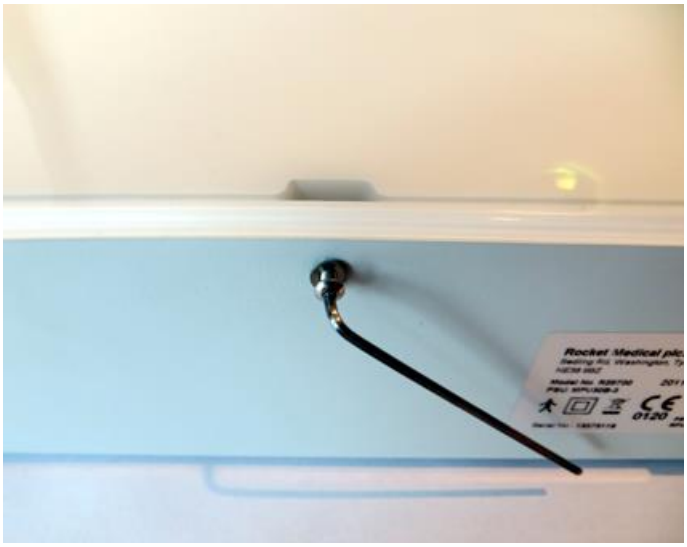
5. ANNUAL SERVICE

5.1 Replacing the inlet and exhaust filters

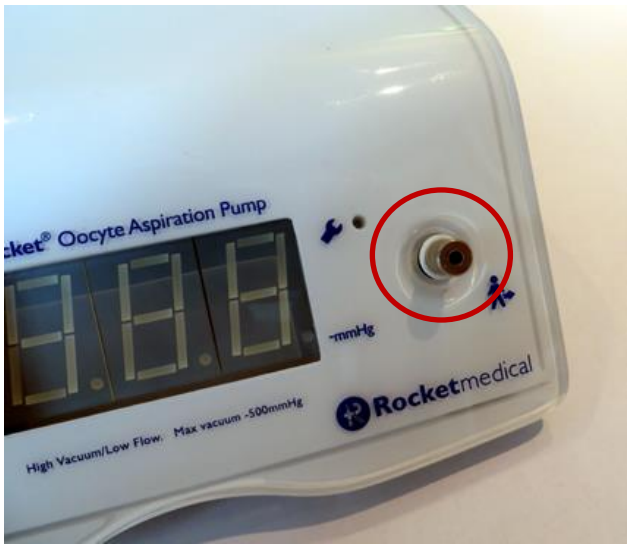
WARNING: Observe precautions for handling electrostatic discharge sensitive devices

1. Lay the pump on a clean surface, protecting the casing from scratches.
2. Remove 3 screws from the rear casing and retain



3. Turn the pump over and remove 3 screws from the front lower casing and retain

4. Remove white silicone retaining ‘O’ ring from vacuum inlet port
5. **CAUTION**: Avoid the use of sharp tools as these may damage the O’ ring.



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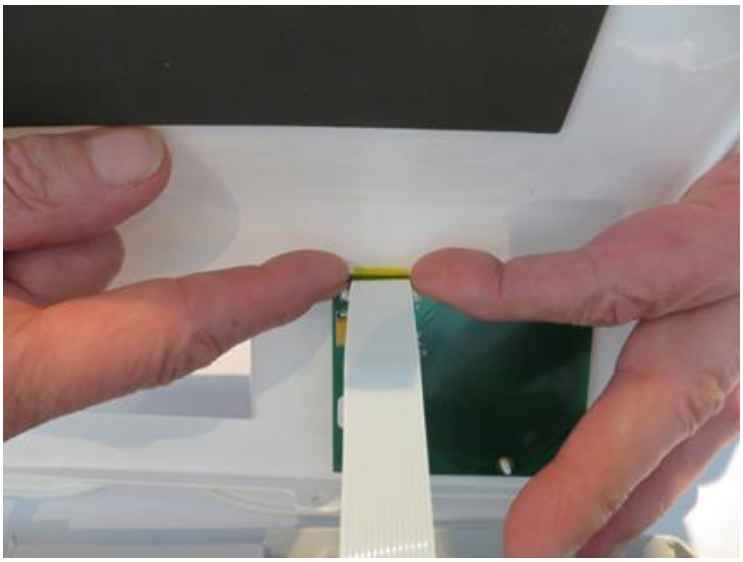
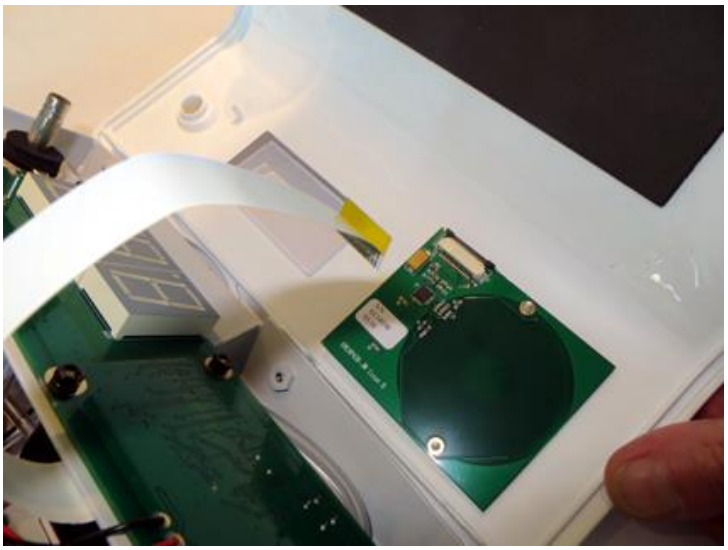
6. Detach ribbon cable from the front panel vacuum controller PCB by lifting the tab

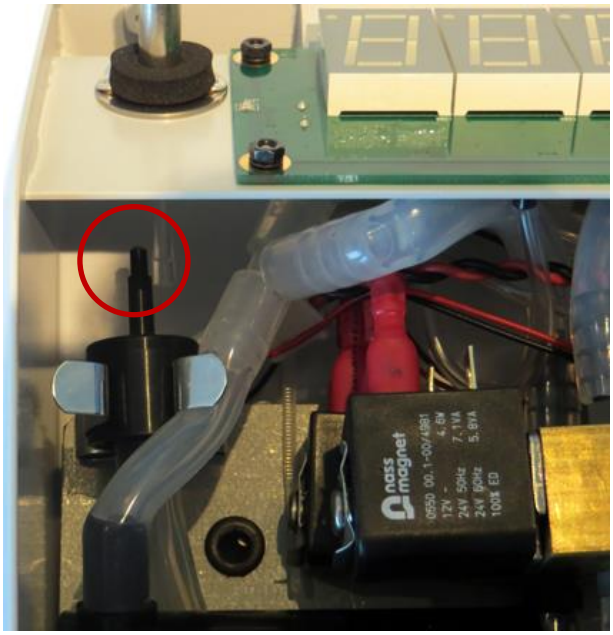


7. Carefully detach the ribbon from the front cover and store securely.



8. Detach patient outlet filter from tube

9. Unclip filter from spring clip, discard and replace filter.



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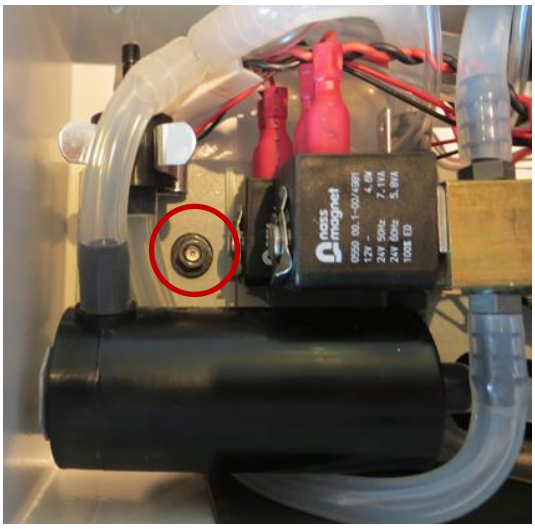
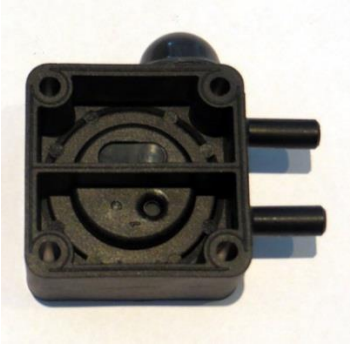
5.2 Replacing the pump valve & diaphragm set

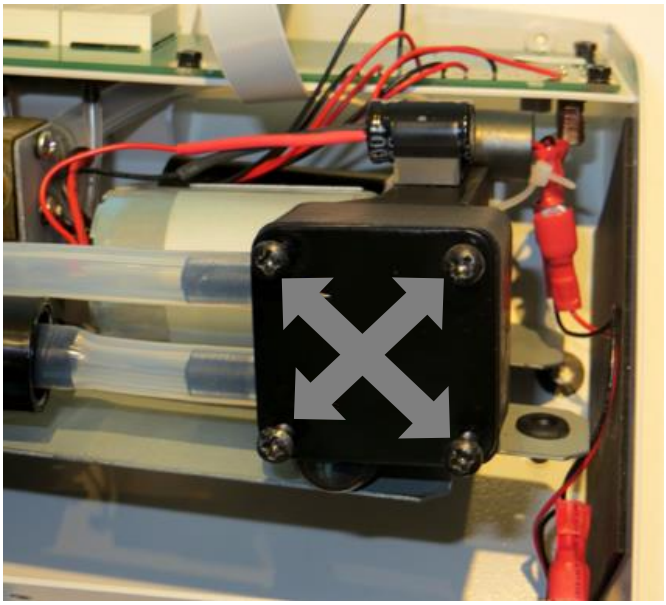


9. Unscrew two securing nuts and lift out chassis to gain access to pump head.

10. Angle chassis to support on casing

11. Unscrew 4 screws form the pump head in a crosswise manner to prevent distortion of the pump head

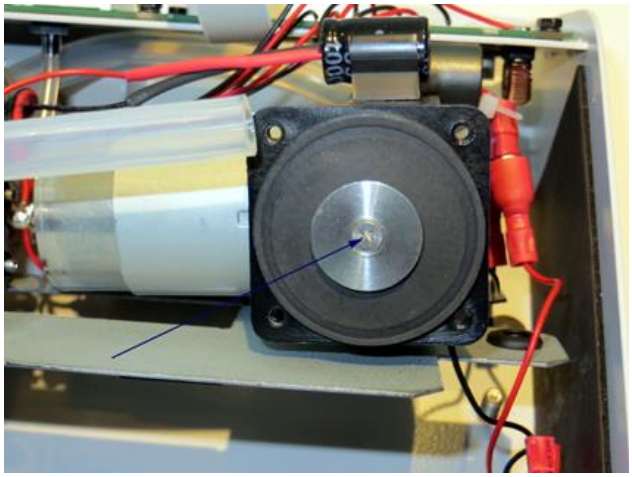




12. Discard and replace the pump head/valve module

IMPORTANT

13. **CAREFULLY** remove the diaphragm by unscrewing the centre screw (arrowed)



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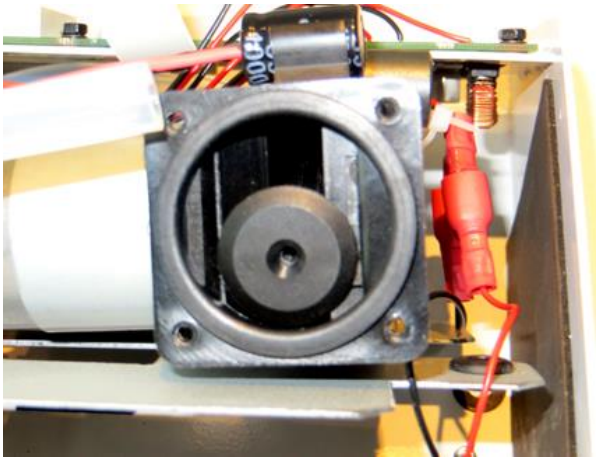
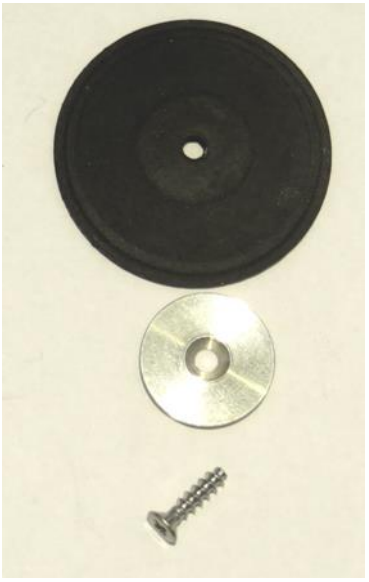
14. Remove the diaphragm to reveal the piston head.
15. Ensure the piston is free to move and that there is no contamination or corrosion evident.



16. Discard old diaphragm and replace.
17. Centralise piston into housing and re-attach diaphragm, plate and screw.

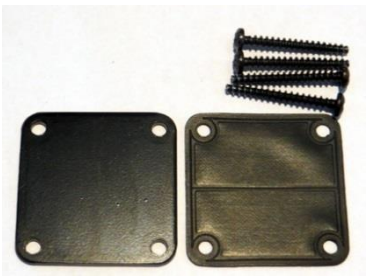
DO NOT OVERTIGHTEN SCREW

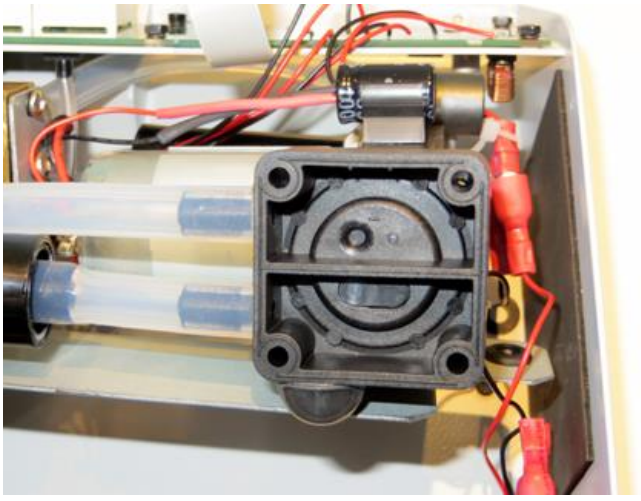


IMPORTANT

IMPORTANT: Note valve head orientation

18. Discard old head gasket and replace with new component.





IMPORTANT

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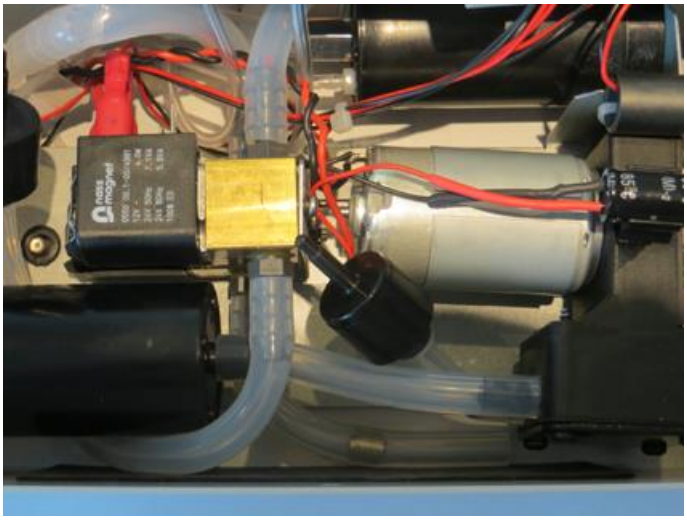
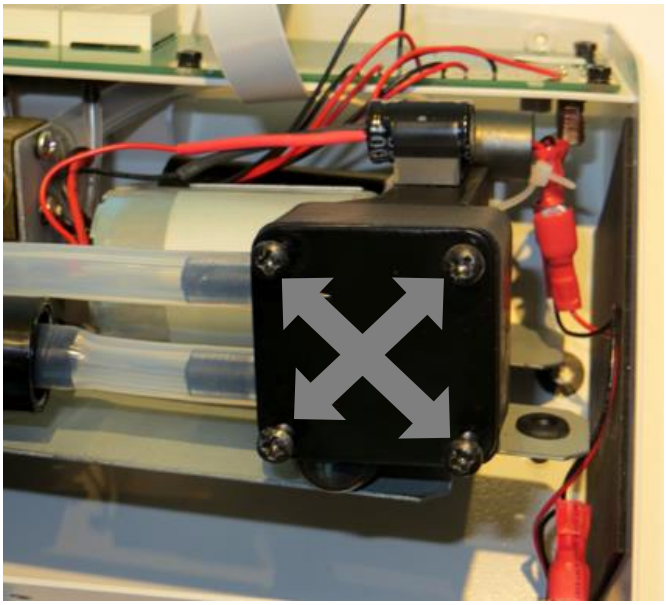
19. Re-attach inlet vacuum tubing to TOP port
20. Re-attach exhaust filter to BOTTOM port.
21. Relocate exhaust filter in bottom of case



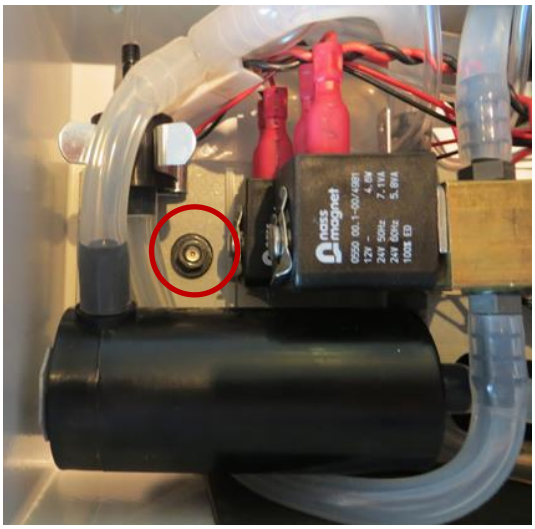
22. Tighten screws in a crosswise fashion to avoid distorting the pump head.

IMPORTANT

DO NOT OVER TIGHTEN



23. Return chassis into casing
24. Re-tighten two securing nuts.



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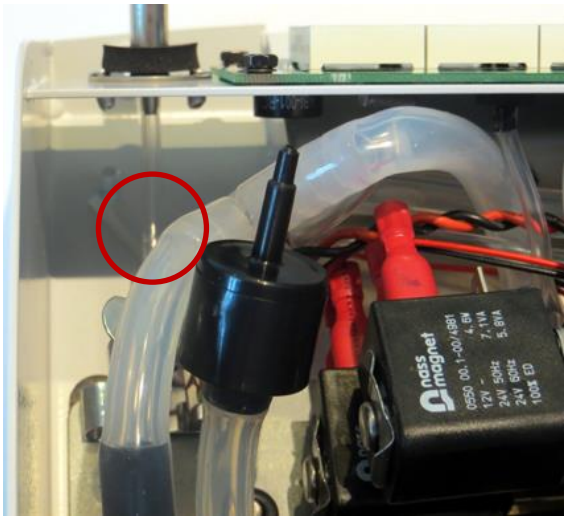
5.3 Reassembling the chassis into the casing

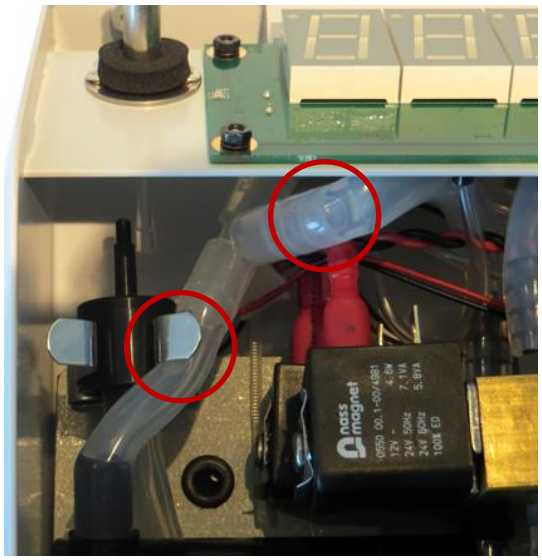
VERY IMPORTANT

25. Pass patient outlet filter underneath tubing and re- attach filter to patient connection port tube.



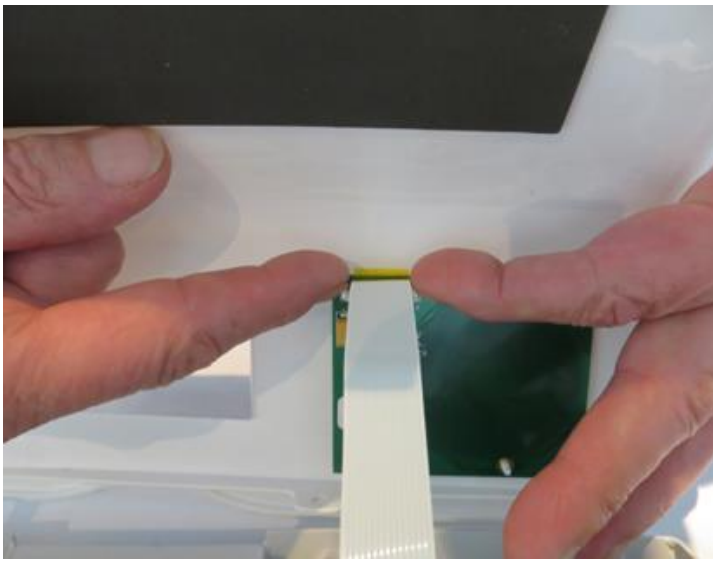
26. Re-clip filter into spring clip

27. Ensure tubing is not trapped by spring clip and correctly routed to avoid occlusion



28. Re-attach ribbon cable from PCB to the front panel vacuum controller PCB by lifting the tab

29. Carefully inserting the ribbon and closing the tab securely.



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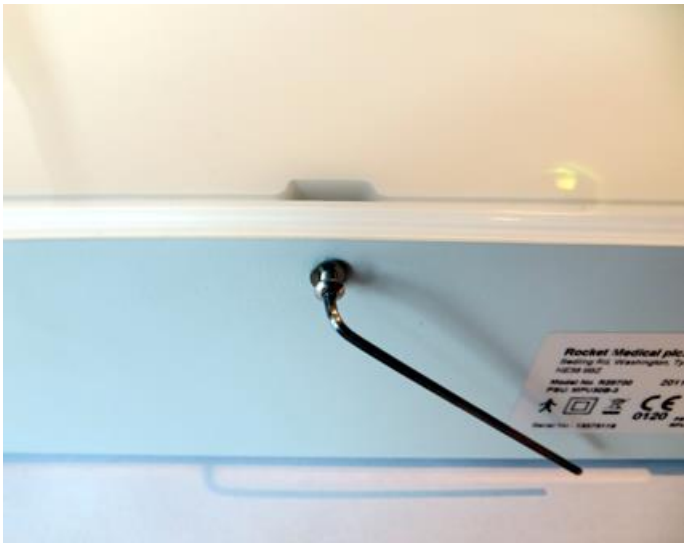
IMPORTANT
DO NOT OVER TIGHTEN THE SCREWS

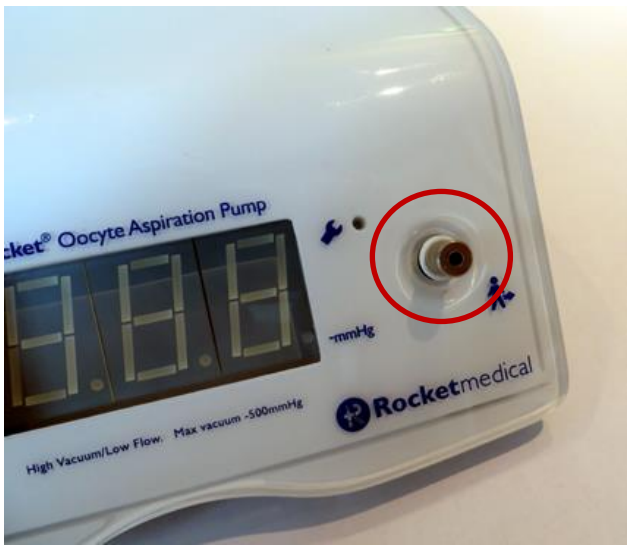
30. Lay the pump on a clean surface, protecting the casing from scratches.
31. After re-assembling the upper casing to the lower frame, re-install 3 screws to the rear casing



32. Turn the pump over and re-install 3 screws to the front lower casing.

CAUTION: Avoid the use of sharp tools as these may damage the O' ring.

33. Re-install the white silicone retaining 'O' ring to the vacuum inlet port.



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6. POST SERVICE INSPECTION

1. Attach 240V Main cable to 12V Power Supply Unit (PSU) Model number: MPU30B-3 and connect to an electrical supply 240VAC 50Hz. The power supply module is self-regulating to generate 12VDC
2. Attach 12V lead to rear input port on the Rocket Digital Oocyte Aspiration Pump (RDOAP)

3. Attach the footswitch air tubing to the male/female ports on the underside of the pump casing.
4. CHECK for security of attachment

5. .Turn the power switch 0-I ❾ (rear panel) to on
6. **CHECK:** The green power LED (indicated) on the front panel is illuminated.
7. The main display will display an initial value of 100mmHg^{-1}

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8. **CHECK** the main display holds a steady value of 100mmHg^{-1}

On Start-Up, the pump is pre-set to 100mmHg^{-1} suction

9. Place a finger on the control surface and using a rotating motion: The central blue dot is NOT active.
10. **CHECK** to see the display changes in 5 (-mmHg) increments down to 50mmHg and up to a maximum of 300 (-mmHg)
11. **CHECK** the active dial zone will sense the clockwise motion to increase the display in 5mmHg^{-1} increments.
12. **CHECK** using an *anticlockwise* circular motion to decrease the value.

13. **CHECK** that a value of 150-mmHg can be set by selecting the value and holding the finger still for 2 seconds when an audible ‘beep’ will confirm the new setting.
14. **CHECK:** If the new setting is not correctly saved, the value will return to its previous set value in 5-10 seconds’

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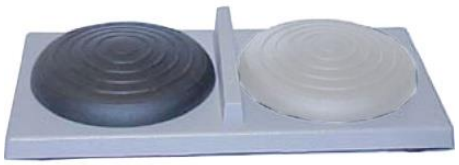
The footswitch control operates on a toggle switch, press once for ON and depress again for OFF



15. Depress the WHITE a pedal once.
16. **CHECK:** The warning tone sounds to indicate activation of the footswitch.

17. **CHECK** that the blue LED has illuminated and is flashing rapidly to confirm suction is active.
18. Stop the suction by depressing WHITE pedal once again.
19. **CHECK** the pump stops immediately and the blue LED has gone out.

Repeat the process for HIGH Vacuum

20. Depress the BLACK pedal once.
21. **CHECK:** The warning tone sounds to indicate activation of the footswitch
22. **CHECK** that the blue LED has illuminated and is flashing rapidly to confirm suction is active.
23. **CHECK** that the ORANGE LED (arrowed right) has also illuminated to confirm HIGH Vacuum is now active.
24. **CHECK** that the display indicates 500 $mmHg^{-1}$
25. Stop the suction by depressing BLACK pedal once again.
26. **CHECK** the pump stops immediately and the blue LED has gone out.

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***WARNING**: Ensure the vacuum levels are within the specified accuracy tolerance before returning the pump to clinical service.*

27. Connect a calibrated vacuum test gauge to the patient port on the pump
28. **RECORD** the Test Gauge serial number and calibration date in the table below

29. Set the pump display to each of the indicated values on the table in turn.
30. Activate the WHITE, low vacuum pedal for the lower values and the BLACK pedal for the Max vacuum value
31. **RECORD:** the values on the gauge in the table below
32. Acceptance criteria: ± 10% of displayed value

Test Gauge	
Serial Number	
Calibration Date	

Display Value $mmHg^{-1}$	Recorded Value	INITIAL TO CONFIRM COMPLETED
100mmHg^{-1}		
VACUUM BLEED TEST	Confirm bleed to 0mmHg in <2.0 seconds	
150mmHg^{-1}		
VACUUM BLEED TEST	Confirm bleed to 0mmHg in <2.0 seconds	
200mmHg^{-1}		
VACUUM BLEED TEST	Confirm bleed to 0mmHg in <2.0 seconds	
MAX 500mmHg^{-1}		
VACUUM BLEED TEST	Confirm bleed to 0mmHg in <2.0 seconds	

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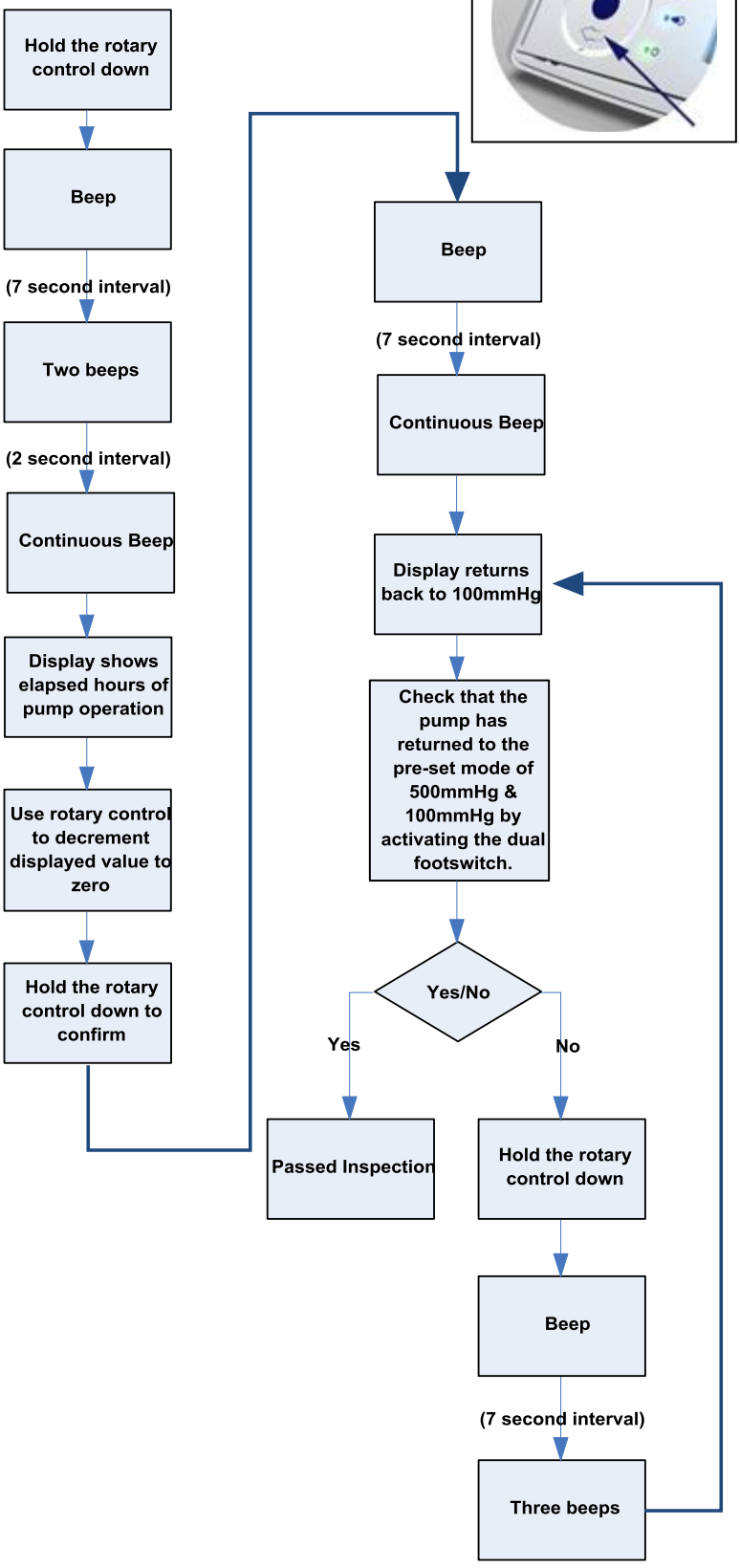
6.1 RESET Pump Timer to ZERO

1. Place a finger on the rotary control surface - initial BEEP
2. HOLD for 7 secs until 2 BEEPS are heard
3. Hold for a further 2 secs until a continuous BEEP is heard
4. Display will show elapsed pump hours
5. **CHECK** using an *anticlockwise* circular motion to decrease the value to ZERO.

6. HOLD rotary control until a single BEEP is heard
7. CONTINUE TO HOLD for further 7 seconds until a continuous BEEP is heard.
8. CHECK the display returns to 100mmHg.
9. CHECK the pump has returned correctly to the PRE-SET mode by activating the black footswitch – reading should show 500mmHg, activate the white footswitch which should show 100mmHg. – PASS
10. If the display does NOT show static values of both 500 and 100mmHg, hold down the rotary control until a single BEEP is heard.
11. Continue to hold for a further 7 seconds until 3 BEEPS are heard. Release the control.
12. CHECK the pump has correctly returned to pre-set mode.



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WARNING:
ELECTRIC SHOCK HAZARD.
Do not immerse the device or power supply.

WARNING: *Do NOT attempt to sterilise the device*

7. CLEANING THE PUMP CASING

At the end of each clinical session, turn off the device at the rear panel ❾ and disconnect the PSU from mains power supply

Using an aqueous 70% alcohol solution (eg. IMS or isopropyl BP) solution, moisten a cloth and wipe all external surfaces of the device. If the surface has become contaminated with proteinaceous material, remove with a light detergent solution before surfacing cleaning with an alcohol solution.

Do NOT use a 100% alcohol or any other solvent to clean the device as this may cause damage to the casing surface and display.

Prevent any fluid from entering the device.

WARNING: *Protect the device from ingress of liquid. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent*

HAZARD:
Do NOT include used consumables as these pose a significant contamination risk

8. YEAR OF MANUFACTURE:

The year in which the device was manufactured is indicated by the first 2 numbers of the serial number.

For example: a serial number starting **11**180776 indicates the device was manufactured in 2011

Units manufactured after 2014 have the year of manufacture stated on the rear label

IMPORTANT
A decontamination certificate MUST be included with every returned pump.

Repair or servicing cannot be commenced unless the service agent is in possession of this certificate

9. RETURNING THE PUMP FOR FACTORY REPAIR OR SERVICE:

All devices to be returned must be prepared as described below for the protection of the servicing team and for safety during transport.

1. Surface clean the pump as described in the Section above
2. Seal in a plastic bag and seal within a second plastic bag.
3. Place in the original packaging.
4. Enclose the following information:
    - Contact name
    - Centre address
    - **Decontamination Certificate**
    - Description of the fault or service required
    - Accompanying Order to authorise servicing – contact your local Customer Services Team for details

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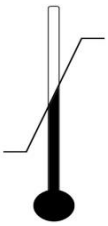
10. STORAGE:

	The device must be stored and operated in temperatures +5°C to +35°C
	The device must be stored in a clean, dry condition, ideally in its original packaging which should be retained to return the unit for servicing Protect the device from ingress of liquid. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent

11. TRANSPORTATION:

<table>
<tr><td> </td><td colspan="2">The device must be transported in temperatures +5°C to +35°C</td></tr>
<tr><td> </td><td colspan="2">The device is FRAGILE and must be transported in its original packaging to ensure protection.
If the original packaging is not available please contact your local Customer Services Agent who will provide replacement packaging.</td></tr>
<tr><td></td><td>Dimensions:
W - 248mm
H - 86mm
D - 194mm</td><td>Weight:
Unit - 2.56Kg
Foot Switch 0.51Kg</td></tr>
<tr><td> </td><td colspan="2">Protect the device from ingress of liquid. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent</td></tr>
</table>

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12. WARRANTY

Rocket Oocyte Aspiration Pumps are sold by **Rocket Medical plc.** under the warranties set forth in the following paragraphs. Such warranties are extended only with respect to the purchase of the Products directly from **Rocket Medical plc.** as new merchandise and are extended to the first Buyer thereof, other than for resale.

For a period of twelve (12) months from the date of shipment the Products are warranted to be free from functional defects in materials and workmanship and to conform to the description of the Products contained in the operating manual and accompanying labels, provided the same is properly operated under conditions of normal use, that annual maintenance and service is performed at an authorised **Rocket Medical plc.** service facility

Removal of any QC seal voids the warranty.

The foregoing warranties shall not apply if the Products have been repaired other than by **Rocket Medical plc.** or other than in accordance with written instructions provided by **Rocket Medical plc.** , or altered by anyone other than **Rocket Medical plc.**, or if the Products have been subject to misuse, negligence, or accident.

Rocket Medical plc. 's sole and exclusive obligation and Buyer's sole and exclusive remedy under the above warranties is limited to repairing or replacing, free of charge, at **Rocket Medical plc.** 's option, Products, which are reported to **Rocket Medical plc.** by mail, telephone or email and which, if so advised by **Rocket Medical plc.**, is thereafter returned with a statement of the observed deficiency, not later than seven (7) days after the expiration date of the warranty, to **Rocket Medical plc.** during normal business address, transport charges prepaid and which, upon **Rocket Medical plc**'s examination, is not found to conform with the above warranties.

Rocket Medical plc. shall not be otherwise liable for any damages including but not limited to incidental damages, consequential damages or special damages.

There are no express or implied warranties which extend beyond the warranties herein above set forth. **Rocket Medical plc.** makes no warranty of merchantability or fitness for a particular purpose with respect to the Products or parts thereof.

13. DISPOSAL:

At the end of the service life of the equipment, this device should be handled and disposed of in accordance with local hospital policy and with regard to all applicable regulations, including but without limitation to, those pertaining to human health & safety and care of the environment.

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14. TECHNICAL SPECIFICATIONS

14.1. CLASSIFICATION

IEC 60601-1

Type of protection against electric shock: Class II

Degree of protection against electric shock: Type B

Vacuum type: high vacuum/low volume

Suitable for continuous operation.

Not suitable for use in the presence of flammable gases.

Not suitable for use in conditions which expose the device to the ingress of water.

Not suitable for sterilisation

14.2. SPECIFICATIONS

Power Input to Pump: 12VDC

Universal Power Supply: 100 - 240VAC

Frequency: 50/60 Hz

Maximum current: 2.5A @ 12V

Environmental conditions: +5°C to +35°C

Service interval: 1000hrs of pump operation.

Dimensions:

- W - 248mm
- H - 86mm
- D - 194mm

Weight:

- Unit - 2.56Kg
- Foot Switch 0.51Kg

Suction Ranges:

- User Set: -50mmHg to -300mmHg^{-1} in 5mmHg increments
- Pre-set: -500mmHg - nominal

Suction Range Accuracy: ±10% at operating range: 100-500mmHg^{-1}

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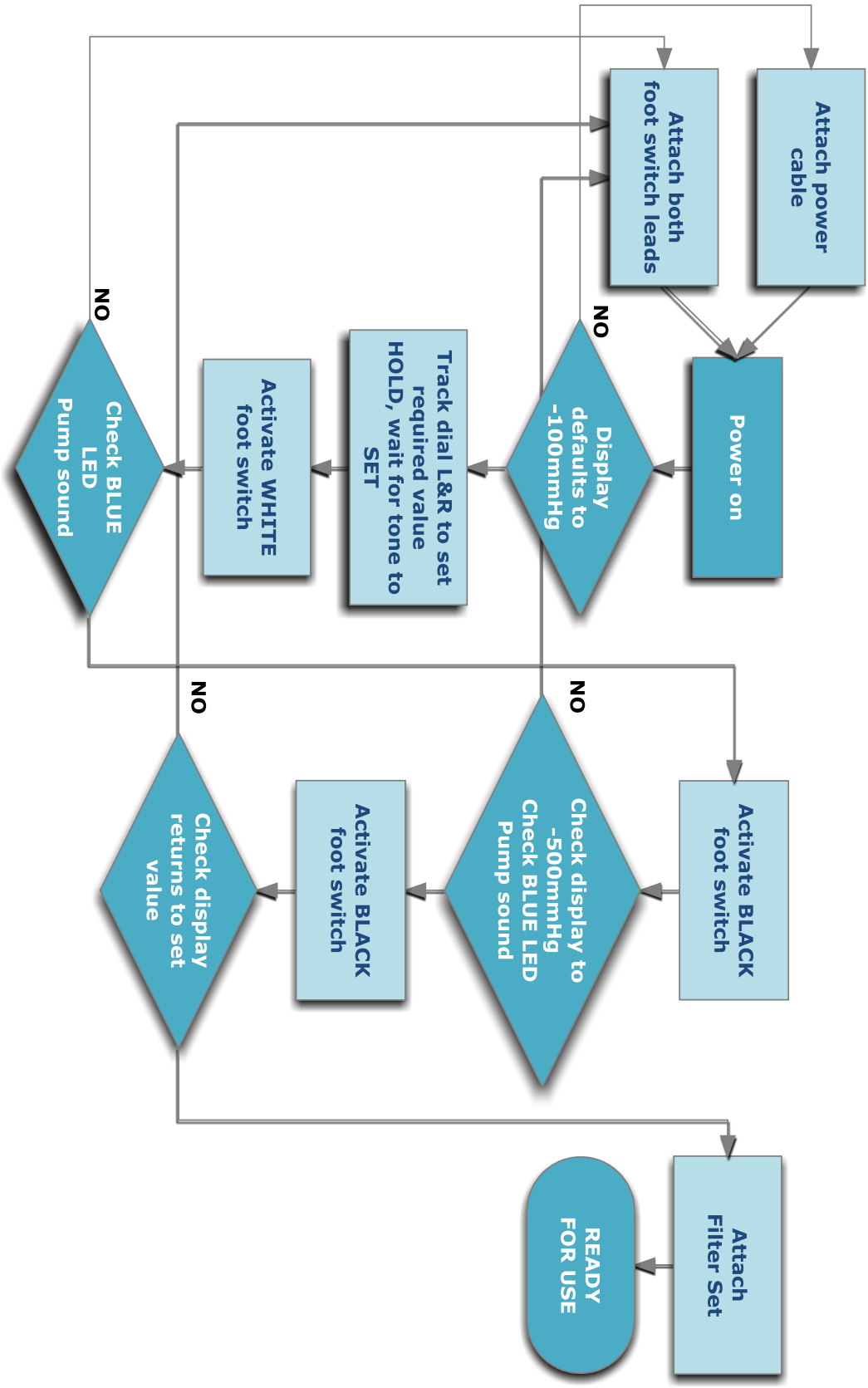
15. DRAWINGS

15.1. Set-up Flow Chart


Attach both foot switch leads
Attach power cable
Power on
Display defaults to -100mmHg
NO
Track dial L&R to set required value HOLD, wait for tone to SET
Activate WHITE foot switch
Check BLUE LED Pump sound
NO
Activate BLACK foot switch
Check display to -500mmHg Check BLUE LED Pump sound
NO
Activate BLACK foot switch
Check display returns to set value
Attach Filter Set
READY FOR USE

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